



1651

Please type a plus sign (+) inside this box →



PTO/SB/21 (08-00)  
Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)		Application Number	09/716,841
		Filing Date	November 17, 2000
		First Named Inventor	BRIESEWITZ, ROGER
		Group Art Unit	1651
		Examiner Name	NAFF, DAVID M.
Total Number of Pages in This Submission	14	Attorney Docket Number	STAN-130
<b>ENCLOSURES (check all that apply)</b>			
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Assignment Papers (for an Application)	<input type="checkbox"/> After Allowance Communication to Group	<b>RECEIVED</b> NOV 08 2002 <b>TECH CENTER 1600/25</b>
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences	
<input checked="" type="checkbox"/> Amendment / Reply	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)	
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition	<input type="checkbox"/> Proprietary Information	
<input checked="" type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Status Letter	
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): <b>Return receipt postcard</b>	
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer		
<input type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Request for Refund		
<input type="checkbox"/> Certified Copy of Priority Documents	<input type="checkbox"/> CD, Number of CD(s) _____		
<input type="checkbox"/> Response to Missing Parts/ Incomplete Application			
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	Remarks		
<b>SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT</b>			
Firm or Individual Name	BRET E. FIELD, Reg. No. 37,620		
Signature			
Date	October 29, 2002		

<b>CERTIFICATE OF MAILING</b>			
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date: October 29, 2002.			
Typed or printed name	Donna Macedo		Date
Signature			October 29, 2002

Burden Hour Statement: This form is estimated to take .2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



### CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Typed or Printed  
Name

Donna Macedo

Signature

D. Macedo

Date

10/29/02

<b>Declaration Under 1.132</b>  Address to: Assistant Commissioner for Patents Washington, D.C. 20231	Attorney Docket Confirmation No.	STAN-130
	First Named Inventor	Briesewitz
	Application Number	09/716,841
	Filing Date	November 17, 2000
	Group Art Unit	1651
	Examiner Name	D. Naff
	Title	Bifunctional Molecules Having Modulated Pharmacokinetic Properties and Therapies Based Thereon

Dear Sir:

I, Dr. Roger Briesewitz, do hereby declare as follows:

I am a co-inventor of the above captioned patent application.

I am a co-author of the research publication: Briesewitz et al., Proc. Nat'l Acad. Sci. USA (March 1999) 96:1953-1958.

The presently pending claims have been rejected under 35 U.S.C. 103(a) as made obvious by the publication of Briesewitz *et al.* (1999), in combination with supplemental references.

The cited published article was a description, in part, of the invention conceived by myself, and as such, is not a publication by another. The article lists as co-authors Thomas Wandless and Gerald Crabtree, who are named as co-inventors, and Gregory Ray, who is not named as co-inventors.

As set forth by the court in *In re Katz*, 215 U.S.P.Q. 14; and MPEP §715.01(c), authorship of an article by itself does not raise a presumption of inventorship with respect to the subject matter disclosed in the article. Thus, coauthors may not be presumed to be coinventors merely from the fact of coauthorship.

The conceptualization of these experiments and the formulation of the invention were the work of myself and my coinventors, Thomas Wandless and Gerald Crabtree.

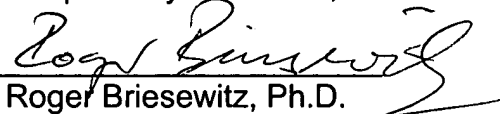
RECEIVED  
NOV 08 2002  
TECH CENTER 1600/2900

Gregory Ray was operating under the direction of myself and/or my listed coinventors and therefore did not make an inventive contribution to the subject matter claimed in the present application.

I hereby declare that all statements made herein of my own knowledge are true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 10/24/02

Respectfully submitted,

By   
Roger Briesewitz, Ph.D.

RECEIVED

NOV 08 2002

## CERTIFICATE OF MAILING

TECH CENTER 1600/2900

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Typed or Printed  
Name

Donna Macedo

Signature

D. Macedo

Date

10/29/02

## RESPONSE TO PAPER NO. 8

Address to:  
Assistant Commissioner for Patents  
Washington, D.C. 20231

Attorney Docket  
Confirmation No.

STAN-130

First Named Inventor

Briesewitz

Application Number

09/716,841

Filing Date

November 17, 2000

Group Art Unit

1651

Examiner Name

D. Naff

Title

Bifunctional Molecules  
Having Modulated  
Pharmacokinetic  
Properties and  
Therapies Based  
Thereon

Dear Sir:

This amendment is responsive to the Office Action dated July 30, 2002.

Please amend the above-identified application as follows.

In the Claims:

16. (Once Amended) A method for modulating at least one pharmacokinetic property of a drug upon administration to a host, said method comprising:

administering to said host an effective amount of a bifunctional molecule of less than about 5000 daltons consisting of said drug or an active derivative thereof and a pharmacokinetic modulating moiety, wherein said bifunctional molecule has at least one modulated pharmacokinetic property upon administration to said host as compared to a free drug control that comprises said drug;

whereby at least one pharmacokinetic property of said drug upon administration to said host is modulated as compared to a free drug control.

sub B'  
A9/2  
P.G. 9  
12/12/02